

## REMARKS

### **I. INTRODUCTION**

In response to the Office Action dated August 26, 2003, claims 1-12 have been cancelled and new claims 13-15 have been added. Claims 13-15 remain in the application. Entry of these amendments, and reconsideration of the application, as amended, is requested.

### **II. CLAIM AMENDMENTS**

Applicants' attorney has made amendments to the claims as indicated above. These amendments were made solely for the purpose of clarifying the language of the claims, and do not introduce new matter. Entry of these amendments is respectfully requested.

The claims are directly supported by the previously pending, and now cancelled, claims. The claims were re-cast as new claims for clarity. New claim 13 incorporates the limitations of previous claims 1, 2, 5-10 and 12. New claim 14 is based on previous claim 6, and new claim 15 is based on previous claim 4.

### **III. EXAMINER INTERVIEW**

Applicants' attorney gratefully acknowledges the assistance and clarification provided by the Examiner during a telephonic interview between Examiner Falk and Applicants' undersigned representative on October 10, 2003. The discussion during this interview centered on claim 8 and also on the Wong-Staal reference. Applicants' attorney has made a good faith effort to prepare this Amendment in a manner consistent with the spirit and content of the interview and to place the application in condition for allowance. Should the Examiner disagree, or find additional issues that must be addressed prior to issuing a Notice of Allowance, the courtesy of a telephone call to Applicants' attorney would be greatly appreciated.

### **IV. PRIOR ART REJECTIONS**

At pages 2-5 of the Office Action, claims 1-2 stand rejected and claims 5, 7, 8, 10, and 11 were rejected under 35 U.S.C. §102(a) as being anticipated by Wong-Staal, U.S. Patent No. 5,650,309 (Wong-Staal); claims 1-3 stand rejected and claims 5, 7, 9, 10, and 11 were rejected under 35 U.S.C. §102(e) as being anticipated by Wong-Staal; claims 1-4 stand rejected and claims 5-7 and 9-12 were

rejected under 35 U.S.C. §102(a) as being anticipated by Sodroski, U.S. Patent No. 5,665,577 (Sodroski); claims 1-4 stand rejected and claims 5-7 and 9-12 were rejected under 35 U.S.C. §102(e) as being anticipated Sodroski; and claims 1, 3-7, and 10-12 were rejected under 35 U.S.C. §102(b) as being anticipated by Poeschla. At pages 6-8 of the Office Action, claims 1-4 stand rejected and claims 5-7 and 9-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Irwin; and under 35 U.S.C. §103(a) as being unpatentable over Naldini and Irwin; and claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Wong-Staal.

While the amendments to the claims render the rejections moot, inasmuch as new claims 13-15 relate to the previous claims, Applicants respectfully traverse these rejections.

Wong-Staal teaches a chimeric vector having a genome containing a (1) cellular transducing portion, and (2) an anti-viral portion. As discussed at column 6, lines 32-58, These two portions are derived from different viruses. The cellular transducing portion is for integrating the vector into the host chromosome. Wong-Staal teaches that a virus such as AAV is selected for this function because it is able to encapsidate reasonably large amount of DNA, contains no endogenous promoter, and has no known mode of pathogenesis. The anti-viral portion is derived from a replication-defective, rescuable viral genome, such as a retrovirus, a lentivirus, and including HIV as a suitable source of the antiviral portion. Wong-Staal teaches a therapeutic vector that relies on the AAV portion for safety as well as its transducing capability, in addition to other practical advantages. This AAV portion is combined with a portion capable of delivering an anti-viral gene. It is this latter function for which the HIV portion is introduced. Wong-Staal does not teach or suggest use of an HIV vector alone for therapeutic use.

The Examiner has referred to column 2, lines 48-56, to support the assertion that Wong-Staal teaches an HIV vector modified to delete an accessory gene such as *nef*. The cited portion of Wong-Staal, however, explicitly refers to the replication-defective, rescuable viral vector portion of the chimeric vector. Column 15, lines 8-40, of Wong-Staal make it clear that, in a therapeutic context, the vector of the Wong-Staal invention is a chimeric AAV/HIV vector which is selected for both safety and efficacy reasons. After discussing the use of the HIV portion to deliver an anti-viral gene, lines 41-60, particularly lines 46-48, Wong-Staal suggests methods to determine suitable anti-viral genes to be delivered by the anti-viral, HIV-derived portion of the chimeric vector, e.g., by introducing HIV vectors carrying anti-HIV genes into cells *in vitro* and evaluating genes that inhibit

HIV (see lines 43-45). Accordingly, Wong-Staal does not teach the use of vectors carrying all of the HIV elements as recited in Applicants' pending claims for inhibiting viral replication in a host infected with HIV.

Moreover, none of the cited references, taken alone or in combination, teach the replacement of 124 base pairs of nef with a polylinker. In addition, these references, taken alone or in combination, fail to teach the use of a vector of Applicants' claim 13, which lacks an anti-viral gene, for a method of treating a host infected with HIV. The combination of these limitations renders them even further removed from the teachings of the cited references.

Accordingly, Applicants respectfully request withdrawal of the rejections based on the prior art and allowance of claims 13-15.

## V. CONCLUSION

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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